



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,362	07/10/2003	Ryuichi Morishita	ANGES-I CIP	6703

1473 7590 11/25/2005

FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
1251 AVENUE OF THE AMERICAS FL C3  
NEW YORK, NY 10020-1105

EXAMINER

VANIK, DAVID L

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/618,362	Applicant(s) MORISHITA ET AL.	
	Examiner David L. Vanik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.  
     4a) Of the above claim(s) 4,5,12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-11 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/6/2003</u> | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Receipt is acknowledged of the Applicants' Oath or Declaration and Information Disclosure Statement filed on 11/18/2003 and 10/6/2003, respectively.

#### ***Election/Restrictions***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (a) NF-KB decoy,
- (b) NF-KB decoy derivative or fragment thereof,
- (c) ets decoy, and
- (d) chimera decoy of NF-KB and ets.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

Art Unit: 1615

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

NF-KB decoys, NF-KB decoy derivatives or fragments thereof, ets decoys, and chimera decoys of NF-KB and ets are specific species of the generic "decoy" genus set forth in the instant claims 1 and 9.

The following claim(s) are generic: claims 1 and 9.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

As stated above, NF-KB decoys, NF-KB decoy derivative or fragments thereof, ets decoys, and chimera decoys of NF-KB and ets are specific species of the generic "decoy" genus set forth in the instant claims 1 and 9.

During a telephone conversation with Shilpa Patel on 11/21/2005 a provisional election was made with traverse to prosecute the invention of the "NF-KB decoy" species, claims 1-3, 6-11, 14-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-5 and 12-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1615

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 8-11, 14-15, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1008352 ('352).

'352 disclose pharmaceutical compositions comprising a NF-KB decoy and a pharmaceutically acceptable carrier (column 3, line 26 – column 4, line 43). According to '352, the pharmaceutically acceptable carrier can be a liposome (column 3, line 55 – column 5, line 10). It should be noted that the use of the pharmaceutical composition “for treatment of a disease” is considered to be a future intended use of the composition and, as such, is given no patentable weight.

The claims are therefore anticipated by EP 1008352 ('352).

Claims 1-3, 6, 8-11, 14-15, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0824918 ('918).

'918 disclose pharmaceutical compositions comprising a NF-KB decoy and a pharmaceutically acceptable carrier (page 2, line 51 – page 3, line 48). According to '918, the pharmaceutically acceptable carrier can be a liposome (page 3, lines 17-53). It should be noted that the use of the pharmaceutical composition “for treatment of a

Art Unit: 1615

disease" is considered to be a future intended use of the composition and, as such, is given no patentable weight.

The claims are therefore anticipated by EP 0824918 ('918).

Claims 1-3, 6, 8-11, 14-15, 17 are rejected under 35 U.S.C. 102(a) as being anticipated by US 6,262,033 ('033).

'033 disclose pharmaceutical compositions comprising a NF-KB decoy and a pharmaceutically acceptable carrier (column 2, line 64 – column 4, line 50). According to '033, the pharmaceutically acceptable carrier can be a liposome (column 3, lines 22-65). It should be noted that the use of the pharmaceutical composition "for treatment of a disease" is considered to be a future intended use of the composition and, as such, is given no patentable weight.

The claims are therefore anticipated by US 6,262,033 ('033).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1615

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1008352 ('352) in view of US 5,225,212 ('212).

The teachings of '352 are set forth above. Although '352 teach a NF-KB decoy-based composition wherein the pharmaceutical carrier is a liposome, '352 does not teach a composition comprising a hydrophilic polymer.

'212 teach liposome-based compositions derivatized with hydrophilic polymers (abstract). A variety of therapeutic compounds, such as proteins and polypeptides, can be incorporated into said liposomes derivatized with hydrophilic polymers (column 3, lines 17-40). According to '212, it is advantageous to derivatize liposomes with hydrophilic polymers because said derivatized liposomes are capable of delivering peptides and proteins into the bloodstream for an extended period of time (column 2, lines 21-53; column 3, lines 17-41; and Example 11). Because, unlike conventional liposomes, liposomes derivatized with hydrophilic polymers are capable of delivering peptides and proteins into the bloodstream for an extended period of time, one of ordinary skill in the art would have been motivated to derivatize the liposomes advanced '352 with hydrophilic polymers. Based on the teachings of '212, there is a reasonable expectation that a liposome-based composition modified with hydrophilic polymers

Art Unit: 1615

would have the ability to deliver peptides and proteins into the bloodstream for an extended period of time. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the liposome-base composition advanced by '352 by derivatizing said composition with hydrophilic polymers in view of the teachings advanced by '212.

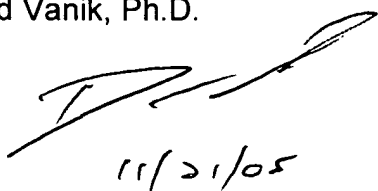
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

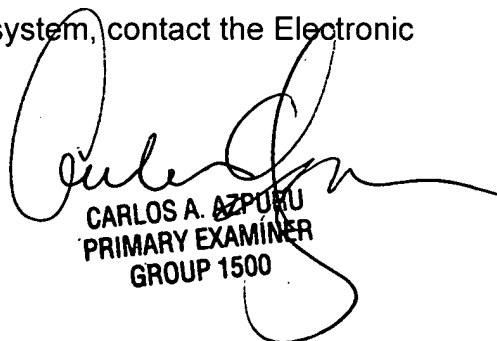
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.



11/21/05



CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500